IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN SALES, LLC, Plaintiff, v. SANDOZ INC., Defendant.	Civil Action No. 2:15-cv-00347 Judge Rodney Gilstrap
SANDOZ INC., Counterclaim Plaintiff, v. ALLERGAN SALES, LLC AND ALLERGAN, INC., Counterclaim Defendants.	

SANDOZ INC.'S REPLY IN SUPPORT OF ITS MOTION FOR EARLIER TRIAL DATE IN LIGHT OF AGREED CONSOLIDATION WITH C.A. 2:12-CV-00207-JRG

Consistent with its position in this litigation (and in earlier-filed actions involving the same parties, the same patent family, and the same accused product), Sandoz asks this Court to resolve the parties' patent dispute as quickly as possible. (*See* 2:09-cv-97 JRG ("*Brim Tim I*"), and 2:12-CV-00207-JRG ("*Brim Tim II*").) After an injunction issued in *Brim Tim I*, Sandoz designed-around the only patent that the Federal Circuit found not invalid and infringed. Consistent with its desire to delay generic competition, Allergan has fought Sandoz's continuous efforts to obtain review of the design-around—efforts that presented an issue of first impression in a Hatch-Waxman case. Believing it to be the fastest and most appropriate avenue, Sandoz filed a Rule 60 motion supported by Federal Circuit precedent on design-arounds generally. Allergan could have agreed to Sandoz's proposed Rule 60 procedure, but it did not. Allergan opposed the motion and refused to engage in discovery, despite Sandoz producing *all* evidence of its design-around, providing five declarations from expert and fact witnesses, and making all witnesses available for deposition.

Although ultimately the courts disagreed with Sandoz that a Rule 60 Motion was an appropriate procedure in Hatch-Waxman cases, it does not follow that Sandoz should be punished for this decision. Nor does it follow that Allergan should be awarded a windfall of additional delay. Allergan agrees that this case should be consolidated with the trial-ready *Brim Tim II*. Because it will not prejudice Allergan and will take relatively little effort to prepare this consolidated action—with only one newly-asserted continuation patent—for trial, Sandoz's motion should be granted.

I. AN EARLIER TRIAL DATE IS WARRANTED AND FEASIBLE

A. Allergan Admits This Case Could Be Prepared For Trial In 15 Months

At the July 30, 2015 status conference, the Court provided trial dates in 2016 for many

cases that are less-developed than this one. (Mot. at 1.) In *Brim Tim I* and *II*, this Court construed many of the patent terms at issue now. Considerable discovery has taken place in those actions that may be applied here. Based on the substantial work already done by the Court and the parties, Sandoz seeks a trial date that is only a few months earlier than other cases that were filed at approximately the same time. In its Opposition, Allergan even admits that this pace is feasible when it states this case could have been tried already—only fifteen months after the last patent was listed in the Orange Book.

Without citing any authority, Allergan relies on the bald assertion that "[i]f Sandoz had fulfilled its obligations under the Hatch-Waxman Act … *this case could have been tried already*." (Resp. at 1 (emphasis added).)[1] As part of these claims, Allergan repeatedly asserts that Sandoz failed to send Allergan a "Paragraph IV" certification and "notice letter" that would have triggered this litigation. This ignores the fact that Sandoz's design-around (like all label-based design-arounds) was filed under 21 U.S.C. § 355(j)(2)(A)(viii), making it a "section viii carve out" for which a new paragraph IV notice letter would have been inappropriate. Regardless, Sandoz sent a new paragraph IV certification at the most appropriate time—promptly after the Federal Circuit ruled on its Rule 60 motion appeal.

Allergan listed U.S. Patent No. 8,748,425 in the Orange Book in July 2014, during the briefing on Sandoz's Rule 60 appeal. Had the Federal Circuit agreed that Sandoz's Rule 60 motion was appropriate, there would have been no need for this lawsuit. While Sandoz could have sent a paragraph IV certification when the '425 was first listed in the Orange Book, Sandoz chose not to clog the courts with multiple lawsuits under multiple procedures. However, shortly

[1] Sandoz has fulfilled *all obligations* under the Hatch-Waxman Act. The FDA agrees, having recently confirmed that Sandoz remains tentatively approved to launch its design-around product pending resolution of patent issues.

after the Federal Circuit ruled against Sandoz's Rule 60 appeal, Sandoz sent a new paragraph IV certification.

Putting aside Allergan's incorrect description of the paragraph IV procedure, Allergan's statement that "*this case could have been tried already*" admits that Sandoz's proposal to try this case next year is more than reasonable. Allergan's statement recognizes that this action could have been tried to resolution *within* 15 months from when the newly-asserted '425 patent issued. Allergan filed suit in early March 2015, and Sandoz seeks a trial 15 months after the case began. (Mot. at 2.) Having told this Court that the case could have been tried within 15 months from the date when the last patent issued, Allergan admits that the case could be tried within 15 months of filing suit.

B. Sandoz Repeatedly Sought To Move The Dispute Forward

Allergan points to Sandoz's decision to file a Rule 60 motion as a time where "Sandoz's pattern of delay relevant to this case then began." (Resp. at 5.) But there has been no such "pattern of delay." Sandoz's request for a modification under Rule 60 only demonstrates Sandoz's intent to have this matter resolved as quickly as possible in an unclear area of the law. (*See Brim Tim I*, ECF Nos. 280, 285.) When these efforts failed in December 2014, Sandoz took immediate alternative action by filing its paragraph IV certification on Allergan's new patent in January 2015. Sandoz informed Allergan at the outset of this case that it should be tried promptly. (Mot. at 3 n.1.) Allergan has no credible explanation for why Sandoz would want to delay a decision on the merits of this case when it is in Sandoz's best interests to achieve a resolution as soon as possible.

C. Allergan Will Not Be Prejudiced By An Earlier Trial

Allergan recognizes that this case could be tried quickly, yet simultaneously claims that Sandoz's request for a trial on that schedule is a "fast track" to trial at Allergan's "detriment."

Allergan supports its inconsistent positions with several flawed arguments.

First, Allergan provides a revisionist account of previous discovery to suggest that it has not already had considerable opportunity to understand Sandoz's non-infringement position. That is complete nonsense as Sandoz provided such an opportunity in the second half of 2013. Sandoz filed its design-around in July 2013, while the *Brim Tim I* case was on appeal. This Court received the Federal Circuit's mandate and resumed jurisdiction on remand on September 16, 2013. The *next day* Sandoz provided Allergan with the details of its design-around, along with five declarations, and an explanation of exactly how Sandoz's design-around does not infringe Allergan's patents. (*See Brim Tim I*, ECF No. 280.) Instead of engaging in discovery, Allergan instead buried its head in the sand regarding Sandoz's design-around.

Sandoz offered all five of its declarants for a deposition. In fact, during the *Brim Tim II* discovery in October 2013, Allergan deposed two Sandoz expert witnesses who provided declarations regarding Sandoz's design-around – Drs. Tanna and Samples. Despite having their declarations in hand for several weeks, Allergan unilaterally announced the day before the depositions that it refused to question them about their design-around declarations. (*See* Reply Decl. of Brian M. Kramer, attached hereto, ¶ 2, Exs. 1 & 2.) Nevertheless, Allergan asked both witnesses specific questions about the patent that is the subject of the design-around. (*Brim Tim I*, ECF No. 299 at 2-3; 11/5/2013 Kramer Decl. ¶¶ 2-3 & Exs. A, B.) Allergan declined an offer of further discovery regarding Sandoz's non-infringement position. (11/5/2013 Kramer Decl. ¶¶ 2-3.) Having done so, Allergan cannot complain that "Sandoz has now had more than two years to develop its new non-infringement and claim construction arguments related to its label amendment[,]" while Allergan has "had no vehicle to conduct [] discovery" on those issues. (Resp. at 9.)

Allergan also argues that "during the depositions of Sandoz's witnesses in [*Brim Tim II*], Sandoz blocked any inquiry about its amended label." (*Id.*) However, Allergan only cites to the deposition transcript of a Sandoz regulatory employee who was appropriately instructed not to disclose conversations with counsel. (*See, e.g.*,*Brim Tim I*, ECF No. 292, Ex. 10 at 217:8-13 (objecting and instructing witness not to answer: "Did anyone communicate to you that an attorney had advised them that Sandoz was advised to delete the word glaucoma?").) Allergan's complaint about that deposition is a red herring diverting attention from Allergan's failure/refusal to take discovery from each of the five witnesses who provided declarations and were willing to sit for depositions.

Allergan also complains that "it was only recently that Sandoz finally produced the remainder of the FDA correspondence related to its design-around, despite possessing it since January of this year." (Resp. at 7.) The suggestion that this additional evidence prevented Allergan from ascertaining the facts is ridiculous. The additional *seventeen* pages of "new" evidence consist of two routine communications with the FDA that do not contain new details of Sandoz's design-around (which has remained unchanged since 2013). Rather than supporting Allergan's prejudice argument, the production underscores that Allergan has had all of the relevant documents for over two years.

Allergan also attempts to paint this case as more complicated than it is. Allergan cites an email in which Sandoz's counsel noted that the parties should be allowed to designate six experts instead of four because combined the parties had already submitted reports or declarations from thirteen experts (twelve of whom have already been deposed) in the previous litigation. (Kramer Decl. ¶ 3; Reichel Decl. Ex. 2 at 1, ECF No. 37-4.) Allergan agreed with Sandoz, yet complains now. Moreover, Allergan's argument makes no sense, as Sandoz's proposal still amounted to a

narrowing of the number of experts from the previous litigation.

D. Sandoz And The Public Are Prejudiced By The Delay

The Hatch-Waxman Act is intended to encourage generic manufacturers to bring affordable medication to market when a branded manufacturer's patents are invalid or not infringed. The patent system is intended to encourage design-arounds. Sandoz has acted consistently with both of these public policies—defeating one of Allergan's patents, and designing around another. Allergan wants to delay Sandoz's opportunity to prove non-infringement of Sandoz's design-around and invalidity of Allergan's remaining patents. This delay prejudices both Sandoz and the public, especially because the delay is unnecessary to provide a fair hearing on the merits of this case. Accordingly, Sandoz requests that the Court set this case for an earlier trial at the Court's convenience.

Dated: September 10, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a). As such, this document was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed. R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email, on this the 10th day of September, 2015.

/s/ William E. Davis, III
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